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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,952	01/16/2007	Nicole Mekideche	1217-0177PUS1	2854
2292 7590 02/12/2008 BIRCH STEWART KOLASCH & BIRCH PO BOX 747			EXAMINER	
			ANDERSON, HEATHER L	
FALLS CHURCH, VA 22040-0747			ART UNIT	PAPER NUMBER
			1655	
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			NOTIFICATION DATE	DELIVERY MODE
			02/12/2008	ELECTRONIC

# Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

, ,						
Office Action Summary		Application No.	Applicant(s)			
		10/596,952	MEKIDECHE, NICOLE			
		Examiner	Art Unit			
		Heather L. Anderson	1655			
Period fo	The MAILING DATE of this communication app or Reply	ears on the cover sheet with the c	correspondence address			
A SH WHIC - Exte after - If NC - Failu Any	ORTENED STATUTORY PERIOD FOR REPLY CHEVER IS LONGER, FROM THE MAILING DANSIONS of time may be available under the provisions of 37 CFR 1.13 SIX (6) MONTHS from the mailing date of this communication. Operiod for reply is specified above, the maximum statutory period or to reply within the set or extended period for reply will, by statute reply received by the Office later than three months after the mailing ed patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tin will apply and will expire SIX (6) MONTHS from a cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).			
Status						
1)⊠	Responsive to communication(s) filed on <u>13 November 2007</u> .					
, —	This action is <b>FINAL</b> . 2b)⊠ This action is non-final.					
3)	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.					
Disposit	ion of Claims					
4) 🖂	Claim(s) 1-3,5-18 and 20-24 is/are pending in	the application.				
	4a) Of the above claim(s) 1-3 and 5-9 is/are withdrawn from consideration.					
5)	5) Claim(s) is/are allowed.					
• • •	Claim(s) <u>10-18 and 20-24</u> is/are rejected.					
•	Claim(s) is/are objected to.	1 2 2				
8)	Claim(s) are subject to restriction and/o	r election requirement.				
Applicat	ion Papers					
9)⊠	The specification is objected to by the Examine	۲.				
10)⊠ The drawing(s) filed on <u>28 June 2006</u> is/are: a)□ accepted or b)⊠ objected to by the Examiner.						
	Applicant may not request that any objection to the					
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11)⊠	The oath or declaration is objected to by the Ex	caminer. Note the attached Office	Action or form PTO-152.			
Priority	under 35 U.S.C. § 119					
12)⊠ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a)⊠ All b)□ Some * c)□ None of:						
1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the priority documents have been received in this National Stage						
application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.						
- <b>,</b>	See the attached detailed Office action for a list	of the certified copies not receive	- · · · · · · · · · · · · · · · · · · ·			
Attachmer	nt(s)	_				
1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  Paper No(s)/Mail Date						
3) 🔯 Infor	ce of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO/SB/08) er No(s)/Mail Date <u>06/29/06</u> .	5) Notice of Informal F				

#### **DETAILED ACTION**

#### Election/Restrictions

Applicant's election with traverse of Group I, claims 10-24 in the reply filed on 13 November, 2007 is acknowledged.

The traversal is on the ground(s) that the presently *amended* claims define novel and non-obvious subject matter. This is not found persuasive.

Applicant admits that the present claims have been amended to specify that the dedifferentiated plant cells are "halophile plant cells" and that this additional limitation is not disclosed by US 2003/0165589 - WO 01/82887. However, the topical application of at least one lyophilisate of dedifferentiated plant cells, which was the corresponding technical feature of Groups I and II, is disclosed by this reference. Based upon the limitations set forth in the previously presented claim 10, the technical feature did not provide a contribution over the art and was not a special technical feature as claimed. The requirement for restriction was therefore properly applied as the claims were written.

The requirement is still deemed proper and is therefore made FINAL.

Claims 4 and 19 have been canceled, and claims 1-3, 5-18 and 20-24 are pending. Claims 1, 5, 10, 12 and 14 have been amended.

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Claims 1-3 and 5-9 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 13 November 2007.

Claims 10-18 and 20-24 are presented for examination on the merits.

#### Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not identify the foreign application for patent or inventor's certificate on which priority is claimed pursuant to 37 CFR 1.55, and any foreign application having a filing date before that of the application on which priority is claimed, by specifying the application number, country, day, month and year of its filing.

Receipt is acknowledged of papers filed under 35 U.S.C. 119 (a)-(d) based on an application filed in France on 29 December 2003. Applicant has not complied with the requirements of 37 CFR 1.63(c), since the oath, declaration or application data sheet does not acknowledge **the filing of the correct foreign application**. A new oath, declaration or application data sheet is required in the body of which the present application should be identified by application number and filing date.

## Specification

The disclosure is objected to because of the following informalities: numerous typographical errors resulting from improper translation (e.g., repeated and unnecessary inclusion of the article "the" and the misspelling of "epidermis").

Appropriate correction is required.

# **Drawings**

The drawings are objected to because they were not translated. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

## Claim Objections

Claim 12 is objected to because of the following informalities: the probable typographical error which results in claim 12 being improperly dependent on withdrawn claim 1, not claim 10. This assumption is based on the fact that this claim is part of a series of claims involving ranges (claims 11-13), and the other two claims depend on claim 10.

Appropriate correction is required.

### Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10-18 and 20-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition topically applied to reconstructed epidermis comprising *Crithmum maritimum* (also known as criste marine or sea fennel), does not reasonably provide enablement for a composition topically applied to human skin comprising any and all species of halophytic plants. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicant has reasonably disclosed/demonstrated that a topical composition comprising *Crithmum maritimum* would be beneficial in several aspects to reconstructed

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epidermis, including a depigmenting effect, an anti-radical effect and a stimulating effect. However, the claims encompass a composition topically applied to human skin comprising any and all species of halophytic plants, so as to provide such functional effects, which is clearly beyond the scope of the instantly claimed/disclosed invention.

Accordingly, it would take undue experimentation without a reasonable expectation of success for one of skill in the art to make and/or use the instantly claimed composition, other than as a composition topically applied to reconstructed epidermis comprising *Crithmum maritimum*, as instantly demonstrated.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-18 and 20-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 10 and 20 are considered to be vague and indefinite due to the use of the phrase "halophile plant cells." The term "halophile" usually refers to the extremophile bacteria. A more properly specific and art-accepted term is "halophyte," a term that is acknowledged by the specification (see, e.g., page 6, lines 14-15). Evidence demonstrating proper usage is given by DeHaan et al. in the attached abstract of the article "Image-derived spectral endmembers as indicators of salinization" which states "Image-derived indicators of vegetation indicators of salinization correspond with the halophytic vegetation comprising the 'succulent' species of Samphire and Sea Blite and

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two species of native grasses" (emphasis added). It is recommended that these claims be amended to read "halophyte cells" or "halophytic plant cells."

All other claims depend directly or indirectly from rejected claims and are therefore, also rejected under 35 U.S.C. 112, second paragraph for the reasons set forth above.

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 10-18 and 20-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Majmudar (US 2005/0123499) in view of Ennamany (WO 03/077881, Derwent abstract and machine translation provided by EPO).

A topical composition comprising at least one lyophilisate of dedifferentiated plant cells from a halophyte is claimed.

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Majmudar beneficially teaches a composition for treating skin that comprises at least one of three ingredients, including sea fennel (criste marine) (see, e.g., paragraph [0010] and entire document). This composition is used to treat aged or damaged skin with symptoms such as mottled pigmentation (see, e.g., [0024]). Sea fennel is described as having many beneficial effects to the skin (se e, e.g., [0033]). Many possible concentrations of the components of this composition are contemplated (see, e.g., [0051]). Whole cells would be present in the composition, so therefore this composition would inherently contain all of the properties and functional effect of the instantly claimed composition. Furthermore, while Majmudar does not teach the preparatory method of dedifferentiating the cells of this halophyte and their subsequent lyophilization, it is taught that the preparation of the source of active ingredients can be obtained by any means known to a person of ordinary skill in the art (see, e.g., [0044]).

Ennamany beneficially teaches a topical composition comprising dedifferentiated plant cells, which are freeze-dried (lyophilized) in the preparation of the composition (see. e.g., the first paragraph of page 1 and the entire machine-translated document). These dedifferentiated plant cells are resulting from in vitro culture (see, e.g., the ninth paragraph on page 1). The advantages of using the technique of culturing dedifferentiated plant cells in vitro which are then subsequently freeze-dried (lyohpilized) is described in detail on page 2, paragraph 10. In particular, freeze-drying (lyophilization) is preferred due to the production of a very fine powder which is easily incorporated in a topical cosmetic and allows the release of active ingredients, all without the use of solvents and extraction procedures which can produce residues.

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It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to prepare the composition of Majmudar using the method by which the composition of Ennamany was produced, based upon the beneficial teachings therein with respect to dedifferentiation and lyophilization of plant cells for use in a topical cosmetic. The adjustment of particular conventional working conditions (e.g., determining the functional effects of such a composition and/or what skin conditions to treat) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claims 10-18 and 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mikimoto (JP 2003-160461, Derwent abstract provided) in view of Ennamany (WO 03/077881, Derwent abstract and machine translation provided by EPO) with evidence provided by the NPS website).

Mikimoto beneficially teaches a topical preparation comprising *Tamarix chinensis* or its solvent extract which has a skin-whitening effect (see e.g., Derwent abstract provided). The genus *Tamarix* is known to be a halophytic species of plants (see, e.g., the paragraph entitled Habitat in the United States in "Saltcedar" from the NPS

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website). Mikimoto does not teach the preparatory method of dedifferentiating the cells of this halophyte and their subsequent lyophilization, although whole cells would be present in the composition. Therefore this composition would inherently contain all of the properties and functional effect of the instantly claimed composition.

Ennamany beneficially teaches a topical composition comprising dedifferentiated plant cells, which are freeze-dried (lyophilized) in the preparation of the composition (see. e.g., the first paragraph of page 1 and the entire machine-translated document). These dedifferentiated plant cells are resulting from in vitro culture (see, e.g., the ninth paragraph on page 1). The advantages of using the technique of culturing dedifferentiated plant cells in vitro which are then subsequently freeze-dried (lyohpilized) is described in detail on page 2, paragraph 10. In particular, freeze-drying (lyophilization) is preferred due to the production of a very fine powder which is easily incorporated in a topical cosmetic and allows the release of active ingredients, all without the use of solvents and extraction procedures which can produce residues.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to prepare the composition of Mikimoto using the method by which the composition of Ennamany was produced, based upon the beneficial teachings therein with respect to dedifferentiation and lyophilization of plant cells for use in a topical cosmetic. The adjustment of particular conventional working conditions (e.g., determining the functional effects of such a composition and/or what skin conditions to treat) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

#### Conclusion

No claims are allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Heather L. Anderson whose telephone number is (571) 270-3051. The examiner can normally be reached on Monday-Thursday, 7:30 AM-5:00 PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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HLA

CHRISTOPHER R. TATE PRIMARY EXAMINED